UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW HAMPSHIRE, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON, and WISCONSIN, the DISTRICT OF COLUMBIA, and the CITY OF CHICAGO, *ex rel*. OSWALD BILOTTA, Plaintiffs and Relator, -against- NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	**No. 11 Civ. 00071 (PGG)**

REPLY MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS RELATOR'S THIRD AMENDED COMPLAINT

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Novartis Pharmaceuticals Corporation ("NPC") respectfully submits this Reply Memorandum of Law in support of its motion to dismiss the Third Amended Complaint ("Complaint" or "Third Amended Complaint") brought under the False Claims Act, 31 U.S.C. § 3729 et seq. ("FCA"), and similar state statutes, by relator Oswald Bilotta ("Relator" or "Bilotta")—an action in which the United States Government and the State of New York have partially intervened and separately filed complaints.

PRELIMINARY STATEMENT

No amount of rhetoric can overcome the legal deficiencies in Relator's Complaint. As demonstrated in NPC's Opening Brief and below, these deficiencies are fatal to Relator's claims and warrant dismissal of the Complaint with prejudice.

First, Relator's kickback-related claims should be dismissed because he lacks standing to maintain separately any kickback-related claims, which he admits have been superseded by the Government's intervention. Moreover, even if Relator had standing (which he does not), those claims are precluded by the FCA's first-to-file bar and the public disclosure bar. Finally, Relator's kickback claims based on conduct that occurred prior to January 2005 are barred by the statute of limitations. (See infra Part I.)

Second, Relator's only remaining federal claim—alleged off-label promotion of the drug Valturna—should be dismissed for failure to meet the pleading standards set forth in Fed. R. Civ. P. 12(b)(6) and 9(b). (See infra Part II.)

Third, the Court should dismiss Relator's state law claims or, alternatively, decline to exercise supplemental jurisdiction, for all the same reasons it should dismiss Relator's federal claims. (See infra Part III.)

ARGUMENT

I. RELATOR'S KICKBACK CLAIMS SHOULD BE DISMISSED.

A. Relator May Pursue Only Those Claims in Which the Government Declined To Intervene.

Relator's argument that "nothing in the statutory language [ ] precludes Relator from participating in the prosecution of the claims in which the Government has elected to intervene" (Opp. at 6-7) misses the point entirely. NPC's present motion does not pertain in any way to Relator's ability to continue to participate in the Government action. Rather, it relates to whether the Relator has standing to maintain, separate from the Government, any kickback claims alleged in his Complaint. In the Second Circuit, when (as here) the government intervenes with respect to a relator's claims, those claims should be dismissed. See United States ex rel. Feldman v. City of New York, 808 F. Supp. 2d 641, 649 (S.D.N.Y. 2011). Indeed, the Government in this action has acknowledged that "[f]ollowing intervention, the Government's claims 'are the operative claims,' and, insofar as they overlap with the relator's claims, 'the relator has no separate free-standing FCA cause of action'". (See 1/17/14 Letter from AUSAs J. Vargas and C. Harwood to Hon. Paul G. Gardephe (citations omitted).)[1] And Relator himself appears to agree with this proposition. (See Opp. at 7 & n.5 ("Relator acknowledges that the

[1] Cases cited by Relator from outside this Circuit (United States ex rel. Klump v. Dynamics Corp., No. 95-cv-1016, 1998 U.S. Dist. LEXIS 21930, at *9 (W.D. Ohio Sept. 30, 1998); United States ex rel. Wilkins v. N. Am. Constr. Corp., 173 F. Supp. 2d 601, 644 (S.D. Tex. 2001); and Miller v. Holzmann, No. 95-cv-1231, 2006 WL 3196433, at *2 (D.D.C. Oct. 31, 2006)) are inapplicable; this district's decision in Feldman is squarely on point and should control. Moreover, contrary to Relator's assertion (Opp. at 8-9), In re Pharm. Indus. Average Wholesale Price Litig. ("AWP"), No. 01-12257, 2007 WL 4287572, at *4 (D. Mass. Dec. 6, 2007), does not "merely" stand for the proposition that a relator's claim is "inextricably tied" to the government's identical claim. The court in AWP dismissed the relator's claims because, once the government intervenes, "there is one claim, the government's". Id. (emphasis added).

Government's Complaint supersedes" his kickback claims and that the Government's claims are "the only operative claims").)

B. Relator's Kickback Claims Are Precluded by the FCA's First-to-File Bar.

As demonstrated in NPC's Opening Brief (at 8-10), a previously filed action by a different whistleblower—Garrity—was pending when Relator filed his action. Garrity's claims were not dismissed by the Court until May 27, 2011, nearly five months after Relator filed his Initial Complaint. (Dillon Reply Declaration ("Dillon Reply Decl.") Ex. A.) Relator's argument that the first-to-file bar should not apply because the Garrity action had been "resolved" is simply wrong: the plain language of the FCA refers to a "pending" action, and Garrity was pending up until August, 2011. 31 U.S.C. § 3730(b)(5).[2]

Relator's attempt to distinguish his Complaint as materially different from the Garrity Complaint is also unpersuasive. The Garrity Complaint alleged the same scheme, involving the same sales division (the cardiovascular ("CV") division) and covering, at least in part, the same time period as Relator's Complaint. These similarities are underscored by the fact that Relator's counsel, who was also Garrity's counsel, apparently shared the Garrity Complaint with Relator while Garrity was still pending and prior to the time that Relator filed his Initial Complaint on January 5, 2011. (Dillon Reply Decl. Ex. A.) That the counsel shared by both Mr. Garrity and Mr. Bilotta is not "lead" counsel (Opp. at 5-6, n.4) does not somehow excuse the similarities between the two complaints (see App. A to NPC's Opening Brief) and, indeed, only

[2] The Hoggett cases cited by Relator (United States ex rel. Hoggett v. Univ. of Phoenix, No. 10-cv-02478, 2012 WL 2681817, at *4 (E.D. Cal. July 6, 2012) ("Hoggett I"), and United States ex rel. Hoggett v. Univ. of Phoenix, No. 10-cv-02478, 2013 WL 875969, at *3 (E.D. Cal. Mar. 7, 2013) ("Hoggett II")), are in accord. The earlier-filed actions in those matters had not only settled, but they had been dismissed by the court before the later complaints were filed.

reinforces the duplicative or "parasitic"[3] nature of the present Complaint.[4] Moreover, those similarities establish that Relator's claims are "materially similar" to Garrity's: Relator merely substituted (in part) a different drug in place of the drugs alleged in the Garrity Complaint. Under these circumstances, the first-to-file bar should apply. See United States ex rel. Sandager v. Dell Mktg., L.P., 872 F. Supp. 2d 801, 807-09 (D. Minn. 2012); United States ex rel. Folliard v. Synnex Corp., 798 F. Supp. 2d 66, 73 (D.D.C. 2011).[5]

Finally, Relator's argument that applying the first-to-file bar in this case would be a "shield against future liability" (Opp. at 13) is unfounded. By its express terms, the first-to-file bar applies only to whistleblowers, not to the Government. The Government may still—and in this case has decided to—investigate and prosecute alleged frauds that it has uncovered as a

[3] Relator's claim that NPC uses the term "parasitic" in order "to malign Relator's action" (Opp. at 2) ignores the fact that the word is a term of art commonly used in reported decisions to refer to duplicative whistleblower complaints.

[4] Despite Relator's contention otherwise (Opp. at 13), United States ex rel. Capella v. United Techs. Corp., No. 94-cv-2063, 1999 WL 464536 (D. Conn. June 3, 1999), supports application of the first-to-file bar. The Capella court stated: "[W]e think it would be useful for the court to be guided by the definition of the word 'parasite,' and ask whether the qui tam case is receiving 'support, advantage, or the like' from the 'host' case . . . 'without giving any useful or proper return'". Id. at *8. Here, there is no dispute that Bilotta's suit received support from the host, Garrity. (See App. A to NPC's Opening Brief.)

[5] As NPC demonstrated in its Opening Brief (at 8-9), the appropriate test is whether the government was on sufficient notice of the alleged fraudulent scheme. Indeed, United States ex rel. Ortega v. Columbia Healthcare, Inc., 240 F. Supp. 2d 8 (D.D.C. 2003), cited by Relator (Opp. at 13), makes clear that the fact that the later complaint describes a different time period or geographic location that could theoretically lead to a separate recovery does not save it from the absolute first-to-file bar (so long as the later-filed complaint alleges the same type of wrongdoing as the first, and the first adequately alleges a broad scheme encompassing the time and location of the later-filed complaint). Id. at 13.

result of the earlier-filed Complaint.[6] What the first-to-file bar prevents is a second recovery on the same alleged conduct by a subsequent whistleblower.

C. The FCA's Public Disclosure Bar Precludes Relator's Claims.

Relator's claims are also precluded by the public disclosure bar. (See NPC Br. at 10-15.) The public disclosure bar applies even where the prior public disclosures do not identify the precise theory of fraud that the relator later alleges, but nonetheless contain "material elements of the 'allegations or transactions' on which the [fraud] claim is based". See United States ex rel. Kirk v. Schindler Elevator Corp., 601 F.3d 94, 103 (2d Cir. 2010) (citing 31 U.S.C. § 3730(e)(4)(A)) (emphasis added), rev'd on other grounds, 131 S. Ct. 1885 (2011); see also United States ex rel. Kirk v. Schindler Elevator Corp., 437 F. App'x 13, 17 (2d Cir. 2011); United States ex rel. Woods v. Empire Blue Cross and Blue Shield, No. 99-cv-4968, 2002 WL 1905899, at *7 (S.D.N.Y. Aug. 19, 2002). The essential elements of the fraudulent kickback scheme alleged by Relator (i.e., that NPC's CV Division engaged in unlawful promotional practices—including making kickback payments to doctors through speaker programs—in connection with the Company's cardiovascular products) are the very same elements of the fraud alleged in Garrity. Accordingly, Relator's claims fall squarely within the public disclosure bar, even under the precedent he himself cites in his papers. See, e.g., United States ex rel. Settlemire v. Dist. of Columbia, 198 F.3d 913, 919 (D.C. Cir. 1999) (Opp. at 14) (noting that a "relator's ability to reveal specific instances of fraud where the general practice has already been publicly

[6] See United States ex rel. King v. Solvay S.A., No. 06-cv-2662, 2013 WL 820498, at *7 (S.D. Tex. Mar. 5, 2013) ("[T]he Government is free to file a claim for related conduct under the statute at any time, and it has been alerted to the alleged fraud due to Relators' complaint. Thus, the court does not believe Abbott (or any other defendant) would feel it is free to engage in wrongdoing that has already been brought to the forefront of the Government's attention simply because the defendant may be able to obtain a dismissal of another qui tam action relating to the conduct.").

disclosed is insufficient to prevent operation of the jurisdictional bar");[7] see also United States ex rel. Pritsker v. Sodexho, Inc., No. 03-cv-6003, 2009 WL 579380, at *9 (E.D. Pa. Mar. 6, 2009), aff'd, 364 F. App'x 787 (3d Cir. 2010); United States ex rel. Dingle v. Bioport Corp., 388 F.3d 209, 215 (6th Cir. 2004).

Relator's claim to be an original source is also meritless. Relator claims that he is an original source because he "personally observed NPC's illicit activities alleged in the Complaint". (Opp. at 15.) This is insufficient pursuant to the clear terms of 31 U.S.C. § 3730(e)(4)(B). Even assuming Relator has independent knowledge, his allegations must "materially add[] to the publicly disclosed allegations or transactions". 31 U.S.C. § 3730(e)(4)(B). Relator does not attempt to explain how his knowledge materially adds to what was already publicly known. He sets forth no "additional compelling fact" or "new and undisclosed relationship between disclosed facts" to meet that standard. See United States ex rel. Lockey v. City of Dallas, No. 11-cv-0354, 2013 WL 268371, at *16 (N.D. Tex. Jan. 23, 2013).[8]

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[7] The other cases cited by Relator to avoid application of the public disclosure bar are similarly unhelpful to his position. Woods, 2002 WL 1905899, at *7, held that it was irrelevant that the previously disclosed information did not make readers or listeners aware of every possible detail of the fraud. In United States ex rel. Blundell v. Dialysis Clinic, Inc., No. 09-cv-0710, 2011 WL 167246, at *6, *8 (N.D.N.Y. Jan. 19, 2011), the court found that the public disclosure bar was not implicated because the publicly disclosed information did not "suggest, infer or accuse defendants of fraud or any fraudulent conduct". And the decision in Hoggett I turned on that fact that relator there alleged "new procedures" that "covered up" a continuation of the previous fraud, which the California District Court found materially added to the publicly disclosed information. 2012 WL 2681817, at *4.

[8] Relator again relies on Hoggett I (Opp. at 16)—a district court case from outside the Second Circuit. NPC respectfully submits that United States ex rel. Chen v. EMSL Analytical, Inc., No. 10-cv-7504, --- F. Supp. 2d ---, 2013 WL 4441509, at *9 (S.D.N.Y. Aug. 16, 2013), should control here. In Chen, the court held that the relator's knowledge was independent from the publicly disclosed allegations or transactions. Id. at *14. However, it found that such independent knowledge did not materially add to any publicly disclosed allegations or transactions. Id. at *14-15.

D. Relator's Claims Prior to January 2005 Are Barred by the Statute of Limitations.

Relator's reliance upon 31 U.S.C. § 3731(b)(2) to rebut NPC's statute of limitations argument (Opp. at 16-17) is misplaced. As cases in the Second Circuit have held, the 10 year limitations period in § 3731(b)(2) does not apply to relators. See United States ex rel. Thistlethwaite v. Dowty Woodville Polymer, Ltd., 6 F. Supp. 2d 263, 265 (S.D.N.Y. 1998) (finding that under "the clear statutory language" of § 3731(b)(2) this "provision only applies to the government").[9] As much as Relator may wish to "stand[] in the shoes of the Government" for statute of limitations purposes (Opp. at 17), by the clear terms of the statutory language and precedent from within the Second Circuit, he does not. Therefore, Relator's claims prior to January 2005 are untimely and should be dismissed.

II. RELATOR'S CLAIMS RELATED TO ALLEGED OFF-LABEL PROMOTION OF VALTURNA SHOULD BE DISMISSED.

A. Relator's Off-Label Allegations Fail Under Rule 12(b)(6).

As NPC demonstrated in its Opening Brief (at 17-19), Relator's off-label promotion allegations are legally deficient because Relator fails plausibly to allege how any claims submitted to government healthcare programs for reimbursement of Valturna prescriptions were "false". Relator's principal argument in opposition rests on the faulty assumption that, because marketing that targets a sub-population of hypertensive diabetics is "off-label" (in Relator's view), NPC must have caused the submission of "false" claims. However, promotion that results in a claim that is otherwise reimbursable is not actionable under the FCA. See United States ex rel. Rost v. Pfizer, Inc., 253 F.R.D. 11, 16-17 (D. Mass. 2008)

[9] Nor is the motion with respect to the statute of limitations "untimely". A statute of limitations bar is properly raised on a motion to dismiss. See Staehr v. Hartford Fin. Servs. Grp., 547 F.3d 406, 425-26 (2d Cir. 2008).

("Merely alleging off-label marketing . . . is not sufficient, without more, to plead a [F]alse [C]laims [A]ct violation."); United States ex rel. Polansky v. Pfizer, Inc., No. 04-cv-0704, 2009 WL 1456582, at *6-7 (E.D.N.Y. May 22, 2009) (granting motion to dismiss and explaining that "the mere fact that Pfizer may have been violating FDA regulations does not translate into liability for causing a false claim to be filed"); see also NPC Br. at 18, n.10. Thus, it is irrelevant that "Relator's Complaint provides detailed allegations regarding NPC's fraudulent promotion of Valturna, citing specific examples of meetings instructing NPC's representatives to use misinformation to persuade doctors" (Opp. at 19 (citing Cmpl. ¶¶ 108-113)), because he fails plausibly to allege that the Government would not have paid for any resulting Valturna prescriptions, which is what the Government states make a claim "false".[10]

During the period in which NPC promoted Valturna, it was broadly indicated for the treatment of hypertension, with pregnant patients as the only excluded sub-population.[11] The cases cited by Relator in support of his argument that off-label marketing results in false claims

[10] United States' Statement of Interest in Resp. to Def.'s Mot. to Dismiss Counts I and III Through XIX of the Fifth Am. Cmpl. at 5, Polansky, No. 04-cv-0704 (E.D.N.Y. Sept. 24, 2010) (Dillon Decl. Ex. E). It is no answer for Relator to argue that all Valturna prescriptions to diabetic hypertension patients were not reimbursable because they were "neither medically indicated nor necessary". (Opp. at 1.) First, the Government, in the same Statement of Interest, states that a medically accepted—and therefore reimbursable—use of a drug includes any use that is listed on the label as FDA approved; thus, if the use is on label, it is by definition medically necessary and reimbursable. Second, even if somehow there were some claims for Valturna prescribed to a hypertensive patient that were not medically necessary, Relator has failed to identify any such claims, or instances where a doctor wrote such a prescription. (NPC Br. at 17-19.)

[11] Nor is the contraindication as to diabetic hypertensive patients added to the label in 2012 relevant to whether Valturna on-label prescriptions prior to the time are allegedly "false".

are inapposite.[12] Thus, even assuming that NPC promoted Valturna to treat hypertension in a sub-population of diabetic patients, any resulting claims cannot be "false".

B. Relator's Off-Label Allegations Lack the Specificity Required Under Rule 9(b).

Relator's allegations fail under Rule 9(b) for the multiple reasons identified in NPC's Opening Brief. (NPC Br. 19-22.) However, the most glaring deficiency is Relator's failure to plead actual false claims. Relator does not refute that he has failed to plead actual false claims. Instead, citing precedent from outside of the Second Circuit, he argues that he is not required to do so. For this reason alone, his false claim allegations fail under Rule 9(b), as Second Circuit precedent clearly requires pleading of an actual false claim. United States ex rel. Siegel v. Roche Diagnostics, Corp., No. 11-cv-5378, --- F. Supp. 2d ---, 2013 WL 6847689, at *5 (E.D.N.Y. Dec. 30, 2013) ("To be sure, courts in other jurisdictions have held that a plaintiff need not plead the specifics of an actual claim under the FCA. However, courts in this Circuit have required a heightened standard with respect to pleading an actual claim under the FCA.").

Relator further argues that all the claims asserted in his Complaint are entitled to a relaxed standard "in light of the position occupied by Relator". (Opp. at 24, n.15 (citing Boykin v. KeyCorp, 521 F.3d 202, 215 (2d Cir. 2008); United States v. Huron Consulting Grp., No. 09-cv-1800, 2011 WL 253259, at *2 (S.D.N.Y. Jan. 24, 2011)).) Boykin, however, rested upon a

[12] E.g., Blain v. SmithKline Beecham Corp., 240 F.R.D. 179, 182, n.6 (E.D. Pa. 2007) (product liability case that therefore did not address the issue of whether an "off-label" claim is a "false" claim); United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 52-53 (D. Mass. 2001) (involving allegations that defendant promoted a drug for other conditions outside the product's label); Strom ex rel. United States v. Scios, Inc., 676 F. Supp. 2d 884, 886 (N.D. Cal. 2009) (same); Galmines v. Novartis Pharmaceuticals Corp., No. 06-cv-3213, 2013 WL 2649704, at *1-2 (E.D. Pa. June 13, 2013) (alleging marketing to a sub-population that had been expressly excluded from the FDA-approved label); United States ex rel. King v. Solvay, S. A., 823 F. Supp. 2d 472, 483, 513-15 (S.D. Tex. 2011) (finding that relator had plausibly pleaded falsity or materiality hinged on alleged improper influence of compendia and state Medicaid committees by defendant).

finding that the facts were "peculiarly within the opposing party's knowledge", which is not the case here.[13] 521 F.3d at 215. And in Huron, the plaintiff included a chart that outlined specific Medicare cases, and identified "the date of each patient's admission, the length of each patient's stay, billing codes, account balances, cost-to-charge ratios, etc.". 2011 WL 253259, at *2. Relator has not even identified a single doctor to whom NPC allegedly spoke about Valturna, let alone an instance in which a doctor prescribed Valturna for a diabetic patient.

Finally, for the reasons demonstrated in NPC's Opening Brief, Relator has also failed to plead the alleged fraudulent scheme with particularity.[14] (NPC Br. at 21-22.)

III. IN THE EVENT RELATOR'S FEDERAL CLAIMS ARE DISMISSED, RELATOR'S STATE LAW CLAIMS SHOULD BE DISMISSED.

As noted in NPC's Opening Brief (NPC Br. at 23-24), courts routinely decline to exercise supplemental jurisdiction in FCA cases where the federal claims are dismissed and the multitude of similar state law claims remain. See United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., No. 09-cv-1086, 2011 WL 3911095, at *6 (E.D. Va. Sept. 6, 2011) (dismissing FCA claims and declining to exercise supplemental jurisdiction over the remaining 26 state law claims), aff'd on other grounds, 707 F.3d 451 (4th Cir. 2013). Relator offers no compelling justification why his state law claims should not be dismissed.[15]

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[13] Information about Valturna reimbursement claims are in the possession of the government healthcare programs to which they were submitted. Additionally, the Government has already engaged in extensive discovery to which Bilotta was almost certainly privy. Indeed, by his own admission, he has worked with the Government in a cooperative fashion. (Opp. at 7, n.5.)

[14] Having already had the benefit of access to extensive pre-suit discovery undertaken by the Government, as well as specific guidance from this Court at the pre-motion conference and an opportunity to amend his Complaint thereafter, Relator's request for leave to amend should be denied as futile and the Complaint should be dismissed with prejudice.

[15] Nor has NPC waived its arguments with respect to Relator's state law claims. See Fed. R. Civ. P. 12(h)(2)-(3).

CONCLUSION

For the foregoing reasons, the Court should grant NPC's motion to dismiss and dismiss Relator's Complaint, in its entirety, with prejudice.

Dated: January 31, 2014

Respectfully submitted,

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